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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/519,356  | 12/28/2004  | Bertram Cezanne      | MERCK-2952          | 4530             |
| 23599   | 7590        | 01/17/2006           | EXAMINER            |                  |
| MILLEN, WHITE, ZELANO & BRANIGAN, P.C.<br>2200 CLARENDON BLVD.<br>SUITE 1400<br>ARLINGTON, VA 22201 |             |                      | KOSACK, JOSEPH R    |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1626                |                  |

DATE MAILED: 01/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |                                       |  |
|------------------------------|--------------------------------------|---------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/519,356 | <b>Applicant(s)</b><br>CEZANNE ET AL. |  |
|                              | <b>Examiner</b><br>Joseph Kosack     | <b>Art Unit</b><br>1626               |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 December 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-33 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 1-33 are pending in the instant application.

#### ***Election/Restrictions***

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Due to the numerous variables in the claims, e.g. R<sup>1</sup>, R<sup>2</sup>, R<sup>3</sup>, M, etc... and their widely divergent meanings, a precise listing of inventive groups cannot be made. The following groups are exemplary:

Group I, claim(s) 1-25 (in part) and 27-30 (in part), drawn to compounds and compositions of Formula I where the compound is N-[4-(2-iminopyrrolidin-1-yl)phenyl]-2-(3-aminomethyl-phenyl)-5-trifluoromethyl-2H-pyrazole-3-carboxamide classified in class 514, subclass 406, and class 548, subclass 374.1.

Group II, claim(s) 1-25 (in part) and 27-30 (in part), drawn to compounds and compositions of Formula I where the compound is N-[4-(2-thioxopyrrolidin-1-yl)phenyl]-2-(3-aminocarbonylphenyl)-5-trifluoromethyl-2H-pyrazole-3-carboxamide classified in class 514, subclass 406, and class 548, subclass 374.1.

Group III, claim(s) 1-25 (in part) and 27-30 (in part), drawn to compounds and compositions of Formula I where the compound is N-[3-chloro-4-(2-thioxopyrrolidin-1-yl)phenyl]-2-(3-amino-carbonylphenyl)-5-trifluoromethyl-2H-pyrazole-3-carboxamide classified in class 514, subclass 406, and class 548, subclass 374.1.

Group IV, claim(s) 1-25 (in part) and 27-30 (in part), drawn to compounds and compositions of Formula I where the compound is N-[4-(2-iminopyrrolidin-1-yl)phenyl]-2-

(3-aminocarbonylphenyl)-5-trifluoromethyl-2H-pyrazole-3-carboxamide classified in class 514, subclass 406, and class 548, subclass 374.1.

Group V, claim(s) 1-25 (in part) and 27-30 (in part), drawn to compounds and compositions of Formula I where the compound is N-[4-(2-methoxyiminopyrrolidin-1-yl)phenyl]-2-(3-aminocarbonyl-phenyl)-5-trifluoromethyl-2H-pyrazole-3-carboxamide classified in class 514, subclass 406, and class 548, subclass 374.1.

Group VI, claim(s) 1-25 (in part) and 27-30 (in part), drawn to compounds and compositions of Formula I where the compound is N-[3-methyl-4-(2-methoxyiminopyrrolidin-1-yl)phenyl]-2-(3-amino-carbonylphenyl)-5-trifluoromethyl-2H-pyrazole-3-carboxamide classified in class 514, subclass 406, and class 548, subclass 374.1.

Group VII, claim(s) 26, drawn to a method of preparation of compounds of Formula I classified in various subclasses of class 514, 540, 544, 546, 548, and 549.

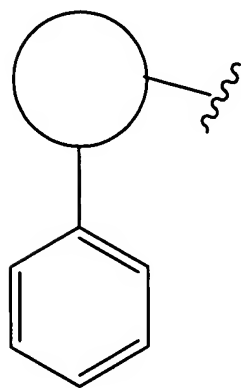
Group VIII, claim(s) 31 and 33, drawn to uses of compounds of Formula I classified in various subclasses of class 514, 540, 544, 546, 548, and 549.

Group IX, claim(s) 32, drawn to kits containing compounds of Formula I classified in various subclasses of class 514, 540, 544, 546, 548, and 549.

In accordance with 37 CFR 1.499, Applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted. Again, **this list is not exhausted**, as it would be impossible under the time constraints due to the sheer volume of subject matter instantly claimed. Therefore, Applicant may choose to elect a single invention by identifying another specific embodiment not listed in the exemplary

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groups of the invention and Examiner will endeavor to group the same. **If Applicant is unable to elect a single invention, Applicant may instead choose to elect a specific compound and Examiner will attempt to group it.** The claims herein lack unity of invention under PCT Rule 13.1 and 13.2 since the compounds defined in the claims lack a significant structural element qualifying as the special technical feature that defines a contribution over the prior art. The compounds claimed contain



, which does not define a contribution over the prior art (see WO 98/28269). The substituents vary extensively and when taken as a whole result in vastly different compounds. Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered proper. Additionally, the vastness of the claimed subject matter and the complications in understanding the claimed subject matter imposes a burden on any examination of the claimed subject matter. The method of use claims will be examined with the elected invention commensurate in scope therewith.

A telephone call was made to Anthony J. Zelano on January 3, 2006 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

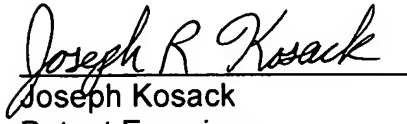
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Kosack whose telephone number is (571)-272-5575. The examiner can normally be reached on M-F 7:15-3:45.

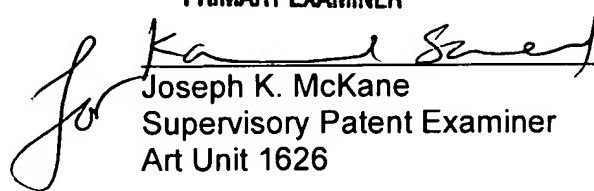
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
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Art Unit 1626

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